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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/961,083	10/30/1997	GIL H. CHOI	PB340P2	6931

22195 7590 06/25/2003

HUMAN GENOME SCIENCES INC
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EXAMINER

HINES, JANA A

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 06/25/2003

32

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application N .

08/961,083

Applicant(s)

CHOI ET AL.

Examiner

Ja-Na Hines

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 17,18 and 198-268 is/are pending in the application.
- 4a) Of the above claim(s) 17,18,198-233,236 and 265-268 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 234,235 and 237-264 is/are rejected.
- 7) ☒ Claim(s) 234 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____. | 6) <input type="checkbox"/> Other: |

DETAILED ACTION

Continued Prosecution Application

1. The request filed on January 18, 2002 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 08/961,083 is acceptable and a CPA has been established. An action on the CPA follows.

Claims 17, 18, 198-233,236 and 265-268 have been withdrawn from consideration. Claims 234, 235 and 237-264 are under consideration in the office action.

Amendment Entry

2. It is noted that the amendment filed February 5, 2002 refers to a change on page 8 line 37, however the words applicants desires to delete and replace do not appear on page 8 line 37, therefore this particular amendment was not entered. Likewise, the amendment at page 15 line 1 to delete and replace was not entered for the same reasons. If applicant desires such amendments, then clarification must be made.

Election/Restrictions

3. Applicant's election with traverse of group IV in Paper No. 30 is acknowledged. The traversal is on the ground(s) that there is no burdensome search for the examiner and that the groups are related.

Applicants argue that there would be no serious burden on the Examiner to search the other groups. Where the related inventions as claimed are shown to be distinct under

Art Unit: 1645

the criteria of MPEP § 806.05(c) - § 806.05(i), the examiner has shown separate classification thereof: This shows that each distinct subject has attained recognition in the art as a separate subject for inventive effort, and also a separate field of search. Examiner has met the requirements to show distinctness and as such has set forth that searching for the strain does not require, for example, the methods are distinct as claimed because they have different methods with different method steps; different functions and the effects have different final outcomes. Each method requires additional unrelated agents, produce different effects and have different functions from the other group. The product inventions were shown to be distinct because the method of attenuation of Group I can be used with a materially different product. The polynucleotide product can be used in a materially different method. The products are distinct as claimed because they have different structures and different uses. Each group has a different function, structure, produces different effects and has a different function from the other group. Therefore, a serious burden would be placed on the examiner to search all of the claims. Therefore applicants' argument that all the claims should be grouped together is not persuasive.

Moreover, applicant arguments that the claims before applicants' amendment and CPA filing were allowable are not persuasive since the claims to new methods and products are drawn to separate and distinct methods and products.

Therefore, the requirement is still deemed proper and is therefore made FINAL.

New Grounds of Objection/Rejection

Claim Objections

4. Claim 234 is objected to because of the following informalities: The claim is dependent upon non-elected claim 201. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 241-264 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

In particular, the claims are drawn to an isolated polypeptide wherein the epitope-bearing portion comprises specifically recited amino acid residues of SEQ ID NO:2.

The specification does not provide evidence of isolated polypeptides wherein the epitope bearing portion comprises the specifically recited amino acid residues of SEQ ID NO:2, such as Arg-10 to Arg-17 of SEQ ID NO:2. The specification beginning at page 23 defines the term epitope bearing portions and epitope bearing polypeptides but fails to teach the identity of portions of polypeptide recited by the instant claims. The specification teaches generic definitions and methods; however the specification does

not state the identity of the epitope bearing portions of SEQ ID NO:2 as claimed. In view of the lack of evidence, it is apparent that Applicants were not in possession of recited epitope bearing portions, at the time of filing the instant application such as Arg-10 to Arg-17 of SEQ ID NO:2 and the like.

A skilled artisan cannot envision the detailed structure of the isolated polypeptide, thus conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. An adequate description requires more than a mere statement that it is part of the invention. The bacterium itself, or a nucleic acid structure is required. See *Fiers v. Revel*, 25 USPQ 2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. V. Chugai Pharmaceutical Co. Lts.*, 18 USPQ2d 1016. The generic characteristics defined by the specification as to what an epitope is of how many amino acids the epitope can be comprised of are purely functional distinctions with no specific reference to the recited claims. Even where there is an actual reduction to practice, which may demonstrate possession of an embodiment of an invention, it does not necessarily describe what the claimed invention is. The instant specification generically describes epitopes, however this description does not describe the claimed isolated polypeptide itself.

In view of the absence of information not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors at the time the application was filed had possession of the claimed invention, the full breadth of the claims fail to meet the written description provision of 35 USC 112, first paragraph.

6. Claims 241-264 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Neither the specification nor originally presented claims provides support for an isolated polypeptide wherein the epitope bearing portion comprises specifically recited amino acid residues of SEQ ID NO:2.

Applicant did not point to support in the specification for an isolated polypeptide wherein the epitope bearing portion comprises specifically recited amino acid residues such as Arg-10 to Arg-17 of SEQ ID NO:2. Moreover, applicant failed to specifically point to support in the specification of the specifically recited portions recited in claims 241-265. Thus, there appears to be no teaching of an isolated polypeptide wherein the epitope bearing portion comprises specifically recited amino acid residues Arg-10 to Arg-17 of SEQ ID NO:2 and the like. Applicant has generically pointed to pages in the instant specification and claims for support of the amendment which are drawn to the definition of epitopes and their description, however it appears that the entire specification appears to fail to recite support for the newly recited specific amino acid residues Arg-10 to Arg-17 of SEQ ID NO:2 and the like. Therefore, it appears that there is no support in the specification. Therefore, applicants must specifically point to page and line number support for the identity an isolated polypeptide wherein the epitope bearing portion comprises specifically recited amino acid residues Arg-10 to Arg-17 of


Art Unit: 1645

SEQ ID NO:2 and the like. Therefore, the new claims incorporate new matter and are accordingly rejected.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na Hines whose telephone number is 703-305-0487. The examiner can normally be reached on Monday-Thursday and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on 703-308-3909. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Ja-Na Hines 
June 24, 2003


LYNETTE R. F. SMITH
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600